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Date of Deposit: August 13, 2008



Attorney Docket No.: 19374-501 NATL

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT(S): Farmer, *et al.*  
SERIAL NUMBER: 09/509,159 EXAMINER: Vera Afremova  
FILING DATE: May 28, 2003 ART UNIT: 1657  
TITLE: TOPICAL USE OF PROBIOTIC BACILLUS SPORES TO PREVENT OR  
CONTROL MICROBIAL INFECTIONS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION OF SEAN FARMER UNDER 37 C.F.R §1.132**

I, Sean Farmer, of Miami Beach, Florida, declare and state as follows:

1. I am a co-inventor of the invention claimed in the above-referenced application and am employed by the named assignee, Ganeden Biotechnology, Inc., San Diego, California.
2. I hold a B.A. degree in Evolutionary Biology from Princeton University and a M.S. degree in Microbiology from University of California Los Angeles. I have been involved in research relating to probiotics for at least 16 years.
3. I have read the Office Action mailed on June 29, 2007 and am familiar with the Examiner's grounds of rejection for lack of written description and lack of enablement.
4. I have performed, or have had performed under my supervision, studies evaluating the therapeutic anti-fungal effect of a probiotic composition containing *Bacillus coagulans* lactic acid-producing bacteria. The probiotic composition contains approximately 1 billion lyophilized vegetative cells of *Bacillus coagulans* bacteria and inert ingredients. The strain of *Bacillus coagulans* bacteria used in the probiotic composition is a strain of *Bacillus coagulans* Hammer (identified as ATCC No. 31284), which is disclosed at page 12, lines 6-8.

Applicants: Farmer  
U.S.S.N.: 10/264,745

5. In studies performed at the Center for Medical Mycology of Case Western Reserve University School of Medicine, and the University Hospitals of Cleveland, OH, the probiotic composition containing one billion *Bacillus coagulans* bacteria was contacted *in vitro* with three pathogenic fungal species: *Candida albicans*, *Candida glabrata*, and *Candida tropicalis*, which are among the species of fungal pathogens known to colonize humans and cause harmful conditions. Inhibition of pathogenic fungal growth was measured visually.

6. Results of these studies demonstrate that the *Bacillus coagulans*-containing probiotic composition was surprisingly effective in inhibiting the growth of *Candida albicans*, *Candida glabrata*, and *Candida tropicalis* as seen in the photographic images of the studies, which are provided in the attached Appendix. Thus, this probiotic composition is an effective treatment of fungal pathogens in human patients.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

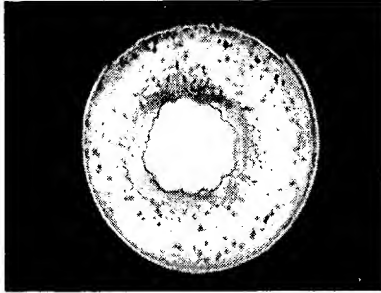


SEAN FARMER

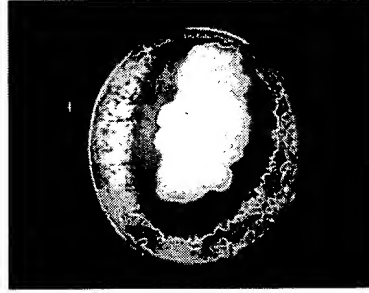
Signed at Miami Beach, FL  
this 13 day of August 2008

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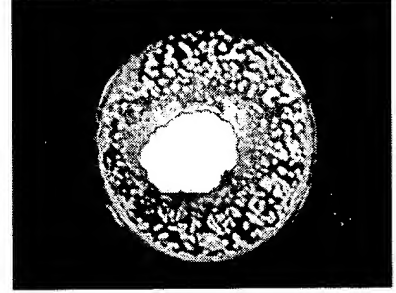
## APPENDIX



*Candida albicans*



*Candida glabrata*



*Candida tropicalis*